



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,248	06/12/2001	Hao Fan	21829/81 (EBC-006)	4829

7590 02/11/2005

Michael L. Goldman
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

EXAMINER

DESAI, ANAND U

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,248	FAN ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 95-130 is/are pending in the application.
- 4a) Of the above claim(s) 95-99 and 103-130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 100-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 100-102, drawn to a protein which elicits a hypersensitive response in plants, said protein comprising three or more hypersensitive response eliciting domains, wherein each domain is comprised of an acidic portion linked to an alpha-helix, said acidic portion having at least 10 amino acids and a pI below 5, wherein at least one of the hypersensitive response eliciting domains is from *Erwinia amylovora*, and at least one of the hypersensitive response eliciting domains comprises amino acids 31 to 57, 116 to 140, or both of SEQ ID NO: 6 in the reply filed on December 28, 2004 is acknowledged. The traversal is on the ground(s) that the claims of the present application are closely related and, therefore, require a common area of search and consideration. This is not found persuasive because the inventions are distinct as described in the restriction requirement mailed November 9, 2004. The inventions are directed to structurally different proteins. Upon review of the restriction requirement, claim 96 can be searched along with the invention of Group II without a serious search burden, and it therefore included in the current examination along with the claims 100-102 of Group II.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 95, 97-99, and 103-130 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on December 28, 2004. This application contains claims 95-99, and 103-130 drawn to an invention nonelected with traverse in Paper filed on December

Art Unit: 1653

28, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Claim 1 is being examined with Group II, claims 100-102. Applicant is reminded that Claim 1 link(s) inventions I, II, III, IV, and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.
4. Claims 1, 96, 100-102 are currently under examination.

Specification

5. The disclosure is objected to because of the following informalities:
6. There appears to be a typographical error within Table 6 on page 56 of the specification. The HR domain identified as “HrpZ_{PSS}-1” for the synthesized region 153-189 appears to be HrpZ_{PSS}-2 (5th one down the HR domain column).

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is directed to a product of nature absent the word, “isolated” or “purified” prior to the word, protein. The naturally occurring protein, HrpZ_{PSS}, from *Pseudomonas syringae* pv. *Syringae* (a pathogen of bean) possesses three hypersensitive response eliciting domains (Applicants disclosure, page 55 or specification, Table 5).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Collmer et al. (U.S. Patent 5,708,139, Reference #2 of IDS submitted June 10, 2002). Collmer et al. disclose an isolated protein from *Pseudomonas syringae* pv. *Syringae* (a pathogen of bean) that elicits a plant defense reaction known as the hypersensitive response. Applicants own disclosure on page 55 of the specification discloses the three hypersensitive response eliciting domains for the protein HrpZ_{PSS}, between amino acids 97 through 308. SEQ ID. NO: 5 of Collmer et al. is the HrpZ_{PSS} protein, which elicits a hypersensitive response in plants, and comprises three hypersensitive response eliciting domains, predicted regions are amino acids 97-132, 153-189, and 271-308, wherein the domain is comprised of an acidic portion linked to an alpha-helix, said

Art Unit: 1653

acid portion having at least 10 amino acids and a pI below 5 (Applicants disclosure, page 55 of specification, Table 5, see also U.S. Patent '139, SEQ ID NO: 5, and claims 1, 4, and 5, current application, claim 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, and 100-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornell Research Foundation (WO 98/54214) in view of Sytkowski et al. (Journal of Biological Chemistry 274(35): 24773-24778 (1999)).

As the applicant states in the application, *Erwinia amylovora*'s hypersensitive response elicitor has two hypersensitive response eliciting domains. The first domain spanning from amino acid 5-64, an acidic region from 5 to 45, an alpha helix from 45 to 64. The second domain from amino acid 103 to 146, with the acidic region from 103 to 131, and an alpha helical

Art Unit: 1653

region from 131 to 146 (page 14, line 48 through page 15, line 8). Cornell (WO 98/54214) teaches an isolated hypersensitive response elicitor protein from *Erwinia amylovora* (page 19, line 25-28) wherein the protein elicits a hypersensitive response in plants (page 6, lines 30-33), and wherein the protein is comprised of the amino acids 1 through 98, or 1 through 218 of the amino acid sequence for the hypersensitive response elicitor protein derived from *Erwinia amylovora* (Claims 1-7, see also Example 8). Cornell does not disclose a protein with three or more hypersensitive response eliciting domains.

Sytkowski et al. discloses the fusion of two erythropoietin domains linked in tandem. A 17-amino acid linker separated the erythropoietin molecules. Both erythropoietin domains of the fusion protein are equally biologically active (see 2nd paragraph of Introduction, Figure 1, and Results section, Construction and Expression of Epo-Epo cDNA). Sytkowski et al. also discloses that the fusion protein consisting of the two Epo domains separated by a peptide linker has significantly enhanced in vitro and in vivo biological activity compared to the monomeric form (see page 24776, 1st sentence of Discussion).

One would have been motivated to construct a protein comprising two of the *Erwinia amylovora* fragments, particularly the fragment comprising two hypersensitive response eliciting domains (amino acids 1-218), as disclosed by Cornell placed in tandem separated by a peptide linker as described by Sytkowski et al., because of the expected increased biological activity of the fused protein. A recombinant protein with either hypersensitive response domains from *Erwinia amylovora* as disclosed by Cornell, or from *Pseudomonas syringae* pv. *Syringae* as disclosed by Collmer, et al. constructed in a tandem (same protein) or hybrid domain (different proteins) repeat orientation would be expected to have an enhanced ability to induce the

Art Unit: 1653

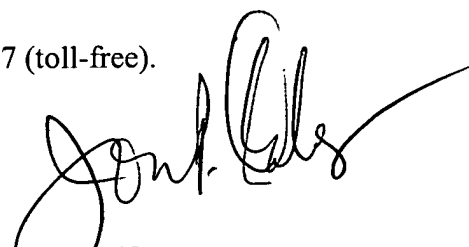
hypersensitive response in plants. The enhanced hypersensitive response confers an enhanced ability to induce disease resistance to plants upon exposure to multiple stresses from pathogens, *Erwinia amylovora* or *Pseudomonas syringae*. Therefore, it would have been obvious to the person having ordinary skill in the art at the time the invention was made to construct a protein comprising three or more hypersensitive response eliciting domains by fusing two biologically active fragments from *Erwinia amylovora*, where the respective fragment could comprise two hypersensitive response eliciting domains individually, such as the fragment from amino acid 1-218 (current application, claims 1, 96, 100-102).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 7, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER